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09/698,454	10/27/2000	Miri Seiberg	JBP0518	5753

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EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/21/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,454

Applicant(s)

SEIBERG ET AL.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) p.16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/03 has been entered.
2. Claims pending are 15-22. Claims 15-22 have been amended.

Information Disclosure Statement

3. Signed/initialed copy of page 16 of 18 of the IDS filed 12/27/01 is attached per Applicant's request. Please note that Derwent Abstracts of Japanese references have been reviewed but will not be cited because they don't have a publication date.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16, 19 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16, 19 and 22 as amended introduce new matter as they use the phrase "non-fractionated soy product". There is no support in the specification for the

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employment of the phrase “non-fractionated” in the claims. The limitation “non-fractionated” was not described in the application as filed, and persons skilled in the art would not recognize in the applicant’s disclosure a description of the invention as presently claimed. The limitation “non-fractionated soy product” is introduced in an attempt to overcome the teachings of the prior art, but does not appear to be a part of the original invention concept. Therefore, it is the examiner’s position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

6. Claims 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of treating acne, does not reasonably provide enablement for the method of preventing acne. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The first paragraph of 35 U.S.C. 112 states, “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...” The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring “ingenuity beyond that to be expected of one of ordinary skill in the art” (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni,

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195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). They include: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or unpredictability of the art, (4) the relative skill of those in the art, (5) the breadth of the claims, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) the nature of the invention

The invention provides a method of treating or preventing acne in the skin of a mammal, said method comprising the step of applying to the skin a topical, skin care composition comprising a non-fractionated soy product, wherein said product comprises a non-denatured soy product and a stabilizing system.

(2) the state of the prior art

Prior art teaches that acne vulgaris is not curable or preventable, but can be treated with various topical agents. See Mysliborski et al., "Therapy for acne vulgaris", Abstract. Anti-

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acne agents are generally known, they include antibiotics, benzoyl peroxide, vitamin A derivatives, salicylic acid, etc. See US 6,558,656 at col. 1, lines 46-60. While teaching treating of acne with various topical agents, the prior art does not teach *preventing* the condition by topical administration of a composition comprising a non-denatured soy product. On the contrary, prior art suggests that acne vulgaris is not preventable. See above.

(3) the predictability or unpredictability of the art

The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. See MPEP 2164.03. In this case, the prior art lacks knowledge in regards to preventing acne by topical administration of a composition comprising a non-denatured soy product. Presently, acne is considered non-preventable. At best, it can be treated or controlled. Further, the Court in *In re Fisher* stated that physiological activity is an unpredictable factor. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). Thus, the unpredictability of the art is high.

(4) the relative skill of those in the art

The relative skill of the those in the art is high.

(5) the breadth of the claims

The claim is broad. It encompasses preventing acne in any mammal by a topical application to the skin of any non-denatured soy product in combination with a stabilizer. The claim does not specify an amount of the soy product or a regimen (e.g. duration and frequency) of the application.

(6) the amount or direction or guidance presented

The instant specification discloses a method for the *treatment* of various skin conditions, including acne. The only pertinent example in the specification (see p. 26, Example 10) is directed to the reduction of the number of acne lesions in a subject having mild acne. Thus, the specification is enabling for such method. The specification does not provide sufficient guidance to allow one skilled in the art to use the claimed method for *preventing* of acne. There is insufficient guidance and objective evidence in the art that would indicate that non-denatured soy products (or any chemical agents) will be able to prevent acne. The fact that various agents were demonstrated to be somewhat effective agents for the treatment of acne, is not an evidence that they will be effective in preventing of the condition. As stated above, the prior art currently does not recognize the possibility of preventing acne by topical treatment.

(7) the presence or absence of working examples

As stated above, the example in the specification is directed to the treatment of said condition rather than the claimed prevention. The specification does not provide any working examples that would indicate the claimed soy products are capable of preventing acne.

(8) the quantity of experimentation necessary

The specification provides insufficient guidance with regard to the claimed method and contains no working examples and no evidence which would allow one of skill in the art to

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predict the efficacy of the claimed method of preventing with a reasonable expectation of success. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success in preventing acne. For the above reasons, it appears that one skilled in the art could not practice the invention with the claimed breadth without an undue amount of experimentation.

Therefore, the instant specification does not provide enablement commensurate with the scope of the claim.

7. Claims 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of treating sunburn, does not reasonably provide enablement for the method of preventing sunburn. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

As discussed above, factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, include: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or unpredictability of the art, (4) the relative skill of those in the art, (5) the breadth of the claims, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) the nature of the invention

The invention provides a method of treating or preventing sunburn on the skin of a mammal, said method comprising the step of applying to the skin a topical, skin care

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composition comprising a non-fractionated soy product, wherein said product comprises a non-denatured soy product and a stabilizing system.

(2) the state of the prior art

Prior art teaches that the best way to prevent sunburn is to avoid sun exposure during the period of peak solar radiation and/or to wear protective clothing. Regular use of sunscreens with an adequate SPF can also help to protect skin from sunburn. See US 6,433,025 issued to Lorenz at col. 9, lines 44-47. Lorenz further teaches that oral administration of the carotenoid astaxanthin can prevent sunburn. See col. 9, lines 52-55. While teaching that the prevention of sunburn is possible, prior art does not teach preventing the condition by topical administration of a compositions comprising a non-denatured soy product. Prior art suggests that, among chemical agents, sunscreens can offer certain level of protection, depending of their SPF, if applied 30 minutes before sun exposure. Still, avoidance of sun exposure remains the best way of preventing sunburn.

(3) the predictability or unpredictability of the art

The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. See MPEP 2164.03. In this case, the prior art lacks knowledge in regards to preventing sunburn by topical

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administration of a compositions comprising a non-denatured soy product. Presently, the best way to prevent sunburn is still to avoid contact between skin and sunrays. Further, the Court in *In re Fisher* stated that physiological activity is an unpredictable factor. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). Thus, the unpredictability of the art is high.

(4) the relative skill of those in the art

The relative skill of the those in the art is high.

(5) the breadth of the claims

The claim is broad. It encompasses preventing sunburn in any mammal (irrespective of skin type) by a topical application to the skin of any non-denatured soy product in combination with a stabilizer. The claim does not specify an amount of the soy product, the SPF of the composition or a regimen (e.g. duration and frequency) of the application.

(6) the amount or direction or guidance presented

The instant specification discloses a method for the *treatment* of various skin conditions, including sun-damaged skin. The only example in the specification that is directed to the prevention of sun-induced damage (see pp. 25-26, Example 8), demonstrates that after 8 weeks of the application (once daily, immediately after shaving) of the soymilk-containing composition of the invention to one side of his face, the sunburn was prevented on that side of the face (i.e. the treated side “was not red, painful or scaly”), as compared to the treatment-free side of the face, following excessive sun exposure of unspecified duration. Further, the Example refers to Figures 5 and 6, which demonstrate the differences in the degree of sun damage between the treated and untreated sides of the face. The Applicant concludes that

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“routine use of soymilk compositions according to this invention, could protect the skin from unexpected strong sun exposure, and reduce redness, scaliness and pain associated with ‘sun burns’”. Thus, the specification, at best, shows that *routine* use of the claimed compositions for a *prolonged* time could possibly *protect* the skin from sun damage. The specification does not provide sufficient guidance to allow one skilled in the art to use the claimed method for *preventing* sunburn in all possible situations (e.g. when the compositions of the invention is applied only once before the sun exposure, or applied routinely but for a short duration, or the sun exposure is prolonged). There is insufficient guidance and objective evidence in the art that would indicate that soy products will be able to prevent sunburn after topical application to the skin. The fact that the soy-containing composition of the instant invention was demonstrated to be somewhat effective in protecting skin of one individual after prolonged routine application of the compositions before the exposure, is not an evidence that it will be effective in preventing sunburn in all situations. As stated above, the prior art currently recognizes that the only way to absolutely prevent sunburn is to avoid sun exposure.

(7) the presence or absence of working examples

As stated above, the example in the specification shows that “routine use of soymilk compositions according to this invention, could protect the skin from unexpected strong sun exposure, and reduce redness, scaliness and pain associated with ‘sun burns’”.

(8) the quantity of experimentation necessary

The specification provides insufficient guidance with regard to the claimed method and contains insufficient evidence which would allow one of skill in the art to predict the efficacy of the claimed method of curing with a reasonable expectation of success. Moreover, the

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nature of the invention and the state of prior art have not provided any reasonable expectation of success in preventing sunburn. For the above reasons, it appears that one skilled in the art could not practice the invention with the claimed breadth without an undue amount of experimentation.

Therefore, the instant specification does not provide enablement commensurate with the scope of the claim.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 15, 17, 18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Voegeli et al. (US 5,322,839).

Voegeli et al. teach cosmetic and dermatological compositions comprising powdered protein fraction from Leguminosae seeds, such as soybeans and lima beans, and a water-soluble preservative, such as metylparaben. See Abstract; col. 2, lines 40-65; col. 3, lines 39-42; Example 1. The soybean protein fraction exhibits trypsin-inhibiting activity and provides hydrating, itch soothing, anti-inflammatory and elasticity increasing effects. See col. 5, lines 2-5; Example 6. The methods claimed in the instant claims are inherent in the reference because the reference explicitly teaches the claimed method step, i.e. applying to the skin a topical, skin care composition comprising a non-denatured soy product and a stabilizer.

Thus, Voegeli et al. teach each and every limitation of Claims 15, 17, 18, 20 and 21.

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Response to Arguments

10. Applicant's arguments filed 7/22/03 have been fully considered but they are not persuasive.

With respect to the Voegeli reference, the Applicant argues that “[n]othing in Voegeli suggests the use of the invention for other than inflammatory skin diseases.” In response, it is noted that Voegeli et al. teach using their compositions not only for the treatment of inflammatory skin diseases, but also for general cosmetic skin care, i.e. for skin moisturizing and increasing skin elasticity. See Examples 13 and 14. Further, Voegeli et al. teach that their compositions soothe or reduce the itching associated with insect bites and psoriasis, reduce skin redness and desquamation. See col. 2, lines 5-39; col. 3, lines 19-24.

Conclusion

11. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541.

The examiner can normally be reached on Monday to Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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10/19/03

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